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Indian Standard (Reaffirmed 2006)

SPECIFICATION FOR TRACHEAL TUBES

PART 2 ORO-TRACHEAL AND NASO-TRACHEAL TUBES OF THE MAGILL TYPE (PLAIN AND CUFFED)

भारतीय मानक

श्वांस नलिकाओं की विशिष्टि

भाग 2 मेजिल टाइप की मौलिक तथा नासिक्य श्वांस नलिकाएं (साधारण और कफ्दार)

UDC 616·231-089·5 : 621·643·2

DESCRIPTORS : MEDICAL EQUIPMENT. ANAESTHESIA. ENDOTRACHEAL TUBES. SPECIFICATIONS. DIMENSIONS. MARKING

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MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

September 1989 **Price Group 5**

Indian Standard

SPECIFICATION FOR TRACHEAL TUBES

PART 2 ORO-TRACHEAL AND NASO-TRACHEAL TUBES OF THE MAGILL TYPE (PLAIN AND CUFFED)

NATIONAL FOREWORD

This Indian Standard (Part 2) which is identical with **ISO 5361/2-1984** 'Tracheal Tubes — Part 2: Oro-tracheal and naso-tracheal tubes of the **Magill** type (plain and cuffed)', issued by the International Organization Standardization (**ISO**), was adopted by the Bureau of Indian Standards on 25 April 1988 on the recommendation of the Anaesthetic, Resuscitation and Allied Equipment Sectional Committee (CPDC 13) and approval of the Consumer Products & Medical Instruments Division Council.

This text of **ISO** standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are however not identical to those used in **Indian** Standards, Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they would be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards the current practice is to use a point (.) as the decimal marker.

This **Indian** Standard is in five parts. The other **four parts** are:

Part *1* General requirements,
Part 3 Murphy type, and
Part 4 Cole type, and
Part 5 Requirements and methods of test for cuffs and tubes.

CROSS REFERENCE

In this Indian Standard the following International Standards are referred to. Read in their respective places, the following:

International Standard	*Indian Standard*	*Degree of Correspondence*
ISO 5361/1-1984 General Tracheal tubes — Part 1 : General requirements	IS : 12504 (Part 1)-1988 Tracheal tubes — Part 1 General requirements	Identical
ISO 5361/5-1984 Tracheal tubes — Part 5 : Requirements and methods of test for cuffs and tubes	IS : 12504 (Part 5)-1988 Tracheal tubes — Part 5 Requirements and methods of test for cuffs and tubes	Identical

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0 Introduction

This International Standard is one of a series dealing with anaesthetic equipment and medical breathing machines, and specifies the dimensions and basic properties of the most commonly used types of tracheal tubes, whether made of rubber or of other elastomeric material. Tubes with walls reinforced with metal or nylon, tubes with shoulders, tapering tubes, or the many types of special tubes devised for use in thoracic surgery, are not specifically covered, although most may be classified by their inside diameter as required by this specification.

While the inside diameter has been specified for size reference, this part of ISO 5361 requires that the outside diameter be marked on the smaller sizes of tube where this information is of greater clinical importance.

Clinical considerations have also dictated the apparently excessive specified length of tubes, because long tubes, sometimes of relatively narrow diameter, may be urgently required, and must therefore be readily available. Cognizance has been taken of developments in the use of pre-cut tracheal tubes supplied as sterile in unit packs (see the table and note).

1 Scope and field of application

This part of ISO 5361 specifies requirements for oro-tracheal and naso-tracheal tubes of the Magili type (plain and cuffed).

2 References

ISO 594/1, *Fittings with a 6 % Luer taper for syringes, needles and certain other medical equipment — Part 1 : General requirements.*1)

ISO *5361, Tracheal tubes —*

Part 1 : General requirements.

Part 5 : Requirements and methods of test for cuffs and tubes.

3 General

Oro-tracheal and naso-tracheal tubes of the Magiii type (plain and cuffed) shall meet the requirements of ISO 5361/1.

4 Dimensions

4.1 The basic dimensions of tracheal tubes shall be in accordance with the table.

4.2 The inside diameter shall be the nominal diameter subject to a tolerance of ± 0,15 mm for size 6,0 and smaller, and subject to a tolerance of ± 0,20 mm for size 6,5 and larger.

4.3 For size 6,0 and smaller the actual outside diameter (OD) shall be within 0,15 mm of the marked outside diameter (OD) [see 9 b)].

5 Curvature of the tube

5.1 The radius of curvature for both oral and nasal tubes shall be 140 ± 15 mm for tubes of size 6,5 and larger.

5.2 This curvature may be omitted if desired from the tip of the bevel to' not more than 30 mm beyond the machine end of the cuff. When this curvature (see figure 3) is so omitted, the straight portion shall be tangential to the curve of the tube.

The curvature may also be omitted from uncuffed tubes of size 6,5 and larger over the same equivalent distance as for cuffed tubes.

6 Bevel

6.1 All tubes shall have an angle of bevel of 38” ± 10°.

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1) At present at the stage of draft. (Revision of ISO/R 594-1967.)

6.2 The end of the tube at the bevel shall be rounded and the orifice(s) shall be free from sharp edges.

6.3 The bevel of oral tubes shall have the opening facing to the left when the tube is viewed towards the concave aspect from the machine end (see figure 1). Nasal tubes may have the bevel facing in either direction.

7 Cuff

7.1 A cuff, if provided, shall be a bonded cuff and shall comply with the requirements of ISO 5361/5.

7.2 For tracheal tubes of size 5,0 and larger, dimension *B* in figures 1 a) and 1 b) shall not exceed 15 mm.

7.3 The maximum distance from the patient end of the tube to the machine end of the inflatable length of the cuff (C) shall be as given in the table [see figures 1 a) and 1 b)].

NOTE -Many cuffs have virtually no residual volume and are consequently easier to pass through the vocal cords than are some high volume cuffs. Small volume cuffs which generally need a relatively high pressure to inflate them are usually satisfactory, when correctly inflated, for anaesthetic use: i.e. for a few hours.

Attention is drawn to the many reports of tracheal damage when tracheal (or tracheostomy) tubes with small volume high pressure cuffs have been used for extended periods as is commonly the case in respiratory care. In these circumstances, it would appear desirable that cuffs should be made of soft material of low extensibility and have a relatively large residual volume. These factors reduce both the required inflation pressure and the pressure exerted on the tracheal wall. Attention is directed to the rapidly growing literature on this subject.

WARNING — Whatever type of cuff is used it is the responsibility of the user to ensure that it is inflated with no more than the minimum amount of air required to provide an effective seal at the desired lung inflation pressure.

8 Mating tubes for cuffs

6.1 The inflating tube, if fitted, shall have an external diameter of not more than 3,0 mm and shall be situated on the concave aspect of the parent tube. The inflating tube shall not encroach on the lumen of the tracheal tube. The dimensions of the inflating tube shall be calculated in accordance with the table and figures 1 a) and 1 b).

6.2 If the inflating tube is attached externally to the tracheal tube between the cuff and the point of separation [see figures 1 a) and 1 b)], the attachment shall be in such a manner that the inflating tube may be partly stripped off the tracheal tube, if required.

6.3 The inflating tube shall be attached to the parent tube and shall join the cuff in such a manner to ensure that there is no undue projection to intertere with clinical use of the tube. The angle between the inflating tube and the parent tube at the point of separation [see figures 1 a) and 1 b)] shall not exceed 45”.

8.4 The inflating tube may be provided with a pilot balloon [see figures 1 a) and 1 b)]. The pilot balloon, if provided, shall be so constructed as to give an indication of inflation of the cuff. Neither the inflating tube nor the balloon shall act as a non-return valve to prevent the intentional evacuation of the cuff.

8.5 The minimum length of dimension S_8 [seg figures 1 a) and 1 b)] shall be 40 mm except where an inflation valve or closure device is provided. Where such a closure device is provided, the length between the pilot balloon and the Luer conical fitting shall be not less than 10 mm to facilitate clamping except where the balloon and valve are built together.

8.6 The free end of the inflating tube may be open, or fitted with an appropriate plug or valve. Where the end is open, it shall be capable of accepting a male conical fitting with a 6% taper (Luer) in accordance with ISO 594/1.

Alternatively, the inflating tube shall be fitted with an insert having a female conical fitting with a 6 % taper (Luer) in accordance with ISO 594/1.

9 Marking

In addition to the general requirements for marking given in part 1 of ISO 5361, tracheal tubes of the Magill type shall be marked as follows:

a) The word “Oral”, “Nasal” or “Oral/Nasal” as appropriate on tubes of sizes 5,0 and larger.

b) For sizes 6,0 and smaller, the outside diameter shall be marked in millimetres.

If both the inside diameter and the outside diameter are marked the marking shall be in accordance with either of the following examples:

4,0 Oral 5,7 or ID 4,0 Oral 5,7 OD.

The figures preceding the word “Oral” denote the internal diameter and should be in larger and bolder type.

c) Cuffed tubes and/or the package shall be additionally marked with the letter S (short) or L (long) as appropriate in accordance with the table.

d) Should the straight portion of the tube extend beyond the machine end of the cuff (see clause 5.2), then this shall be stated on the package, for example by the words "Straight patient end".

e) The marking of the size of the tracheal tube shall be situated as shown in the figures, on the bevelled side of the tube reading from the patient end to the machine end. Plain tubes shall have the size marked in a region equivalent to cuffed tubes of similar size.

Table — Basic dimensions of tracheal tubes

Dimensions in millimetres

Designated size (nominal inside diameter)	Minimal length of tube [see figures 1 a) and 1 b), dimension A]		Maximum distance C from the patient end to the machine end of the inflatable length of the cuff	Distance of point of separation of therinflating tube from the patient end [see figures 1 a) and 1 b), dimensions S_1]	
	Oral, Nasal or Oral/Nasal	Oral "precut" (see note 1)		Short (S)	Long (L)
2,5	140	110	—	—	—
3,0	160	120	—	—	—
3,5	180	130	—		—
4,0	200	140		—	—
4,5	220	150		—	—
5,0	240	160	50	—	—
5,5	270	170	54		—
6,0	280	190	58	—	
6,5	290	210	62	145 ± 10	170 ± 10
7,0	300	230	66	150 ± 10	180 ± 10
7,5	310	240	69	155 ± 10	190 ± 10
8,0	320	260	72	160 ± 10	205 ± 10
8,5	320	260	75	165 ± 10	210 ± 10
9,0	326	270	78	170 ± 10	220 ± 10
9,5	320	280	81	175 ± 10	230 ± 10
10,0	320	280	85	180 ± 10	230 ± 10
10,5	320	280	85	180 ± 10	230 ± 10
11,0	320	280	85	180 ± 10	250 ± 10

NOTES

1 Manufacturers desiring to market packaged sterile oral "precut" tubes with connectors inserted may be guided by the tube lengths shown in thetable. However, the user is cautioned that anatomical variations, conditions of use, lengths of tube inserted or other factors may well result in the use of a tracheal tube either long or too short for a given patient. The necessity remains for expert clinical judgement in selecting the size and length of tracheal tubes.

2 provision has not been made for inclusion of dimension C for cuffed tracheal tubes of sizes 4,5 or less because they are seldom required.

3 Two lengths for dimension S_1 are specified to cater for wide variations in clinical practice.

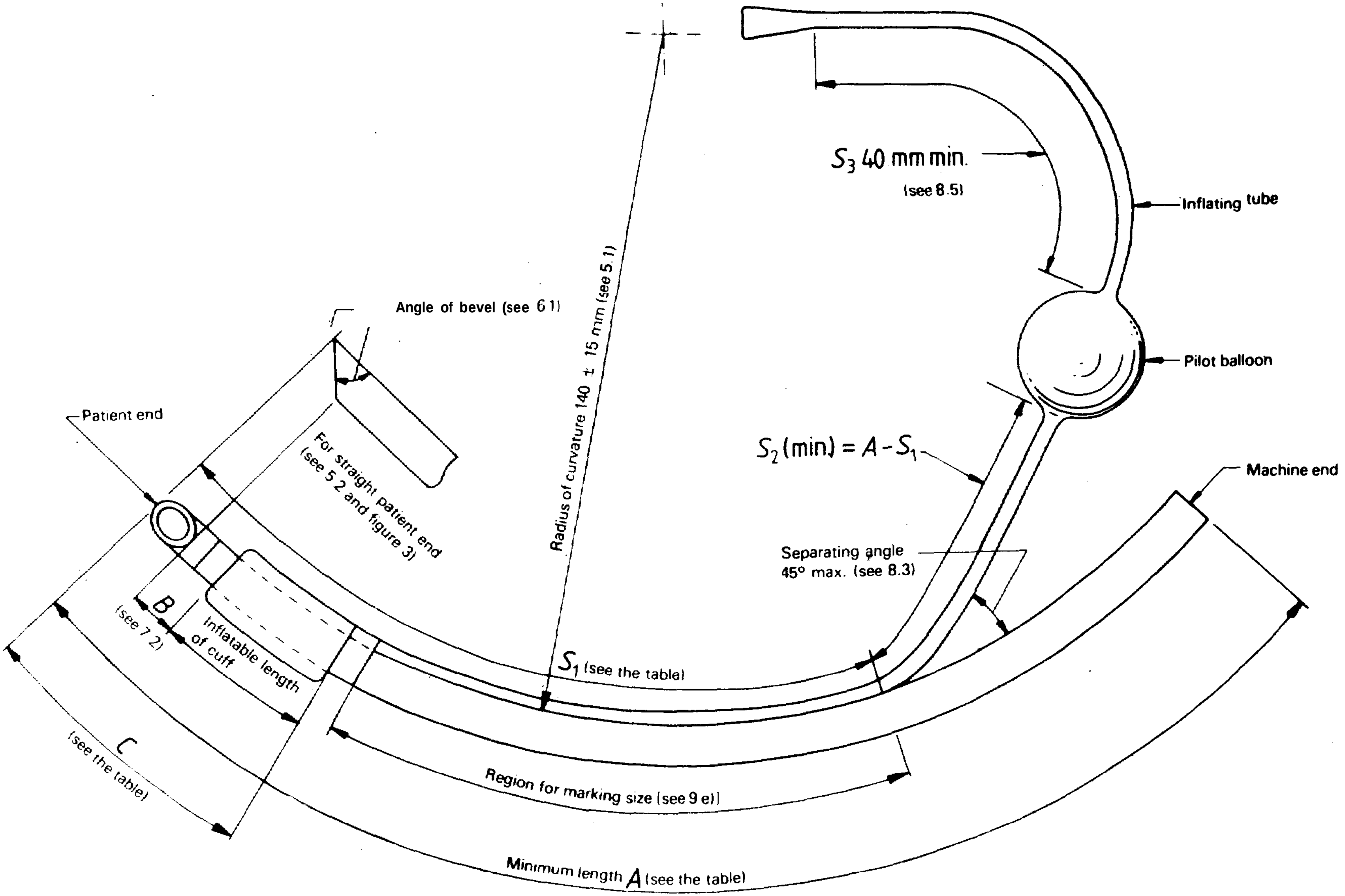
Angle of bevel (see 6.1)
Radius of curvature 140 ± 15 mm (see 5.1)
S_3 40 mm min.
(see 8.5)
Inflating tube
Pilot balloon
S_2 (min) = $A - S_1$
Machine end
Patient end
For straight patient end (see 5.2 and figure 3)
Separating angle 45° max. (see 8.3)
B (see 7.2)
Inflatable length of cuff
S_1 (see the table)
C (see the table)
Region for marking size (see 9 e))
Minimum length A (see the table)

Figure 1 a) — Typical cuffed tracheal tube (**Magill type**)

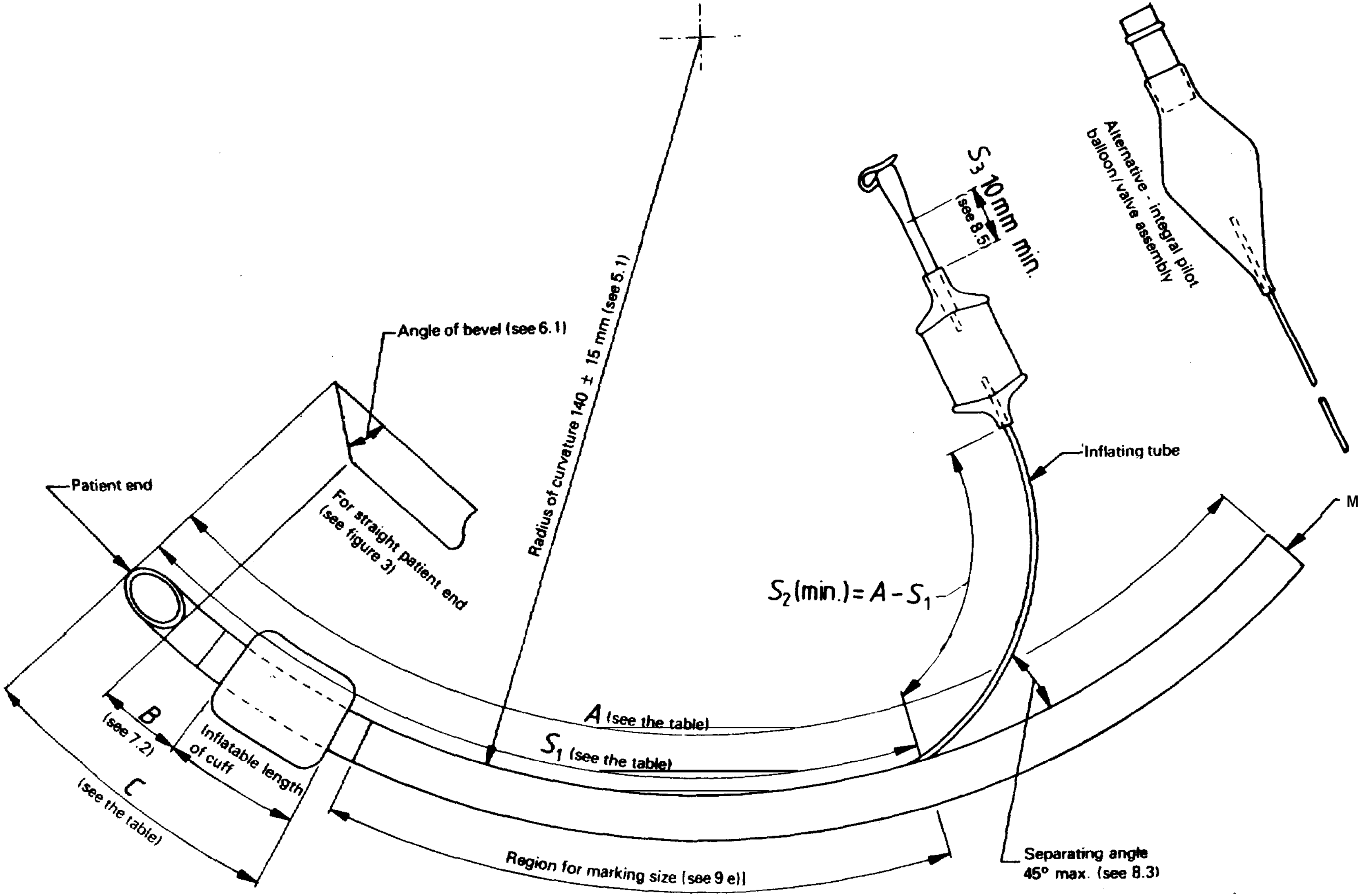
Alternative - integral pilot balloon/valve assembly
S_3 10 mm min. (see 8.5)
Angle of bevel (see 6.1)
Radius of curvature 140 ± 15 mm (see 5.1)
Inflating tube
Patient end
For straight patient end (see figure 3)
Machine end
$S_2(\text{min.}) = A - S_1$
A (see the table)
S_1 (see the table)
B (see 7.2)
Inflatable length of cuff
C (see the table)
Region for marking size (see 9 e))
Separating angle 45° max. (see 8.3)

Figure 1 b) -Typical cuffed tracheal tube (**Magill** type)
(showing alternative design features)

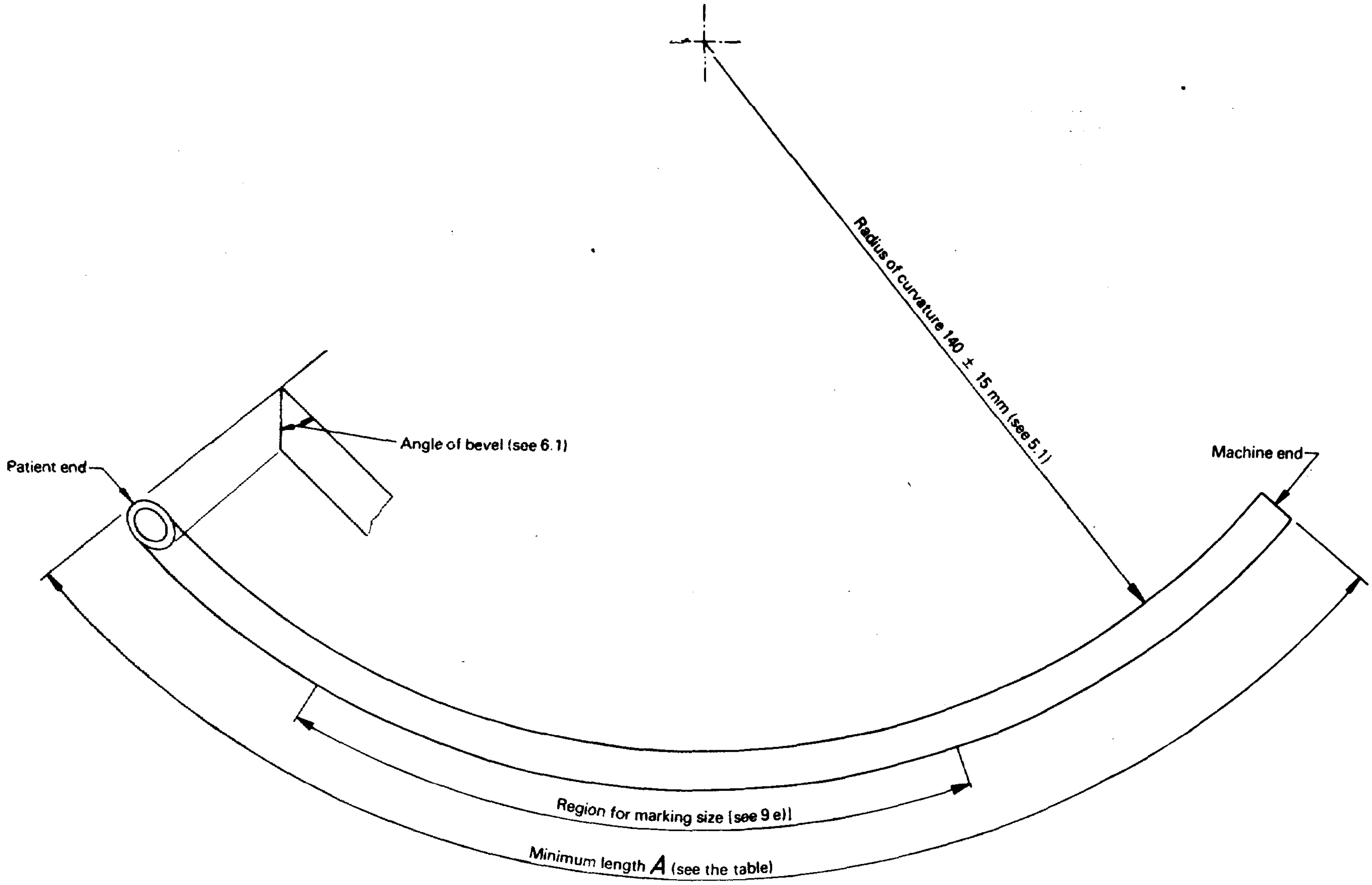
Radius of curvature 140 ± 15 mm (see 5.1)
Angle of bevel (see 6.1)
Patient end
Machine end
Region for marking size (see 9 e))
Minimum length A (see the table)

Figure 2 — Typical plain tracheal tube (Magill type

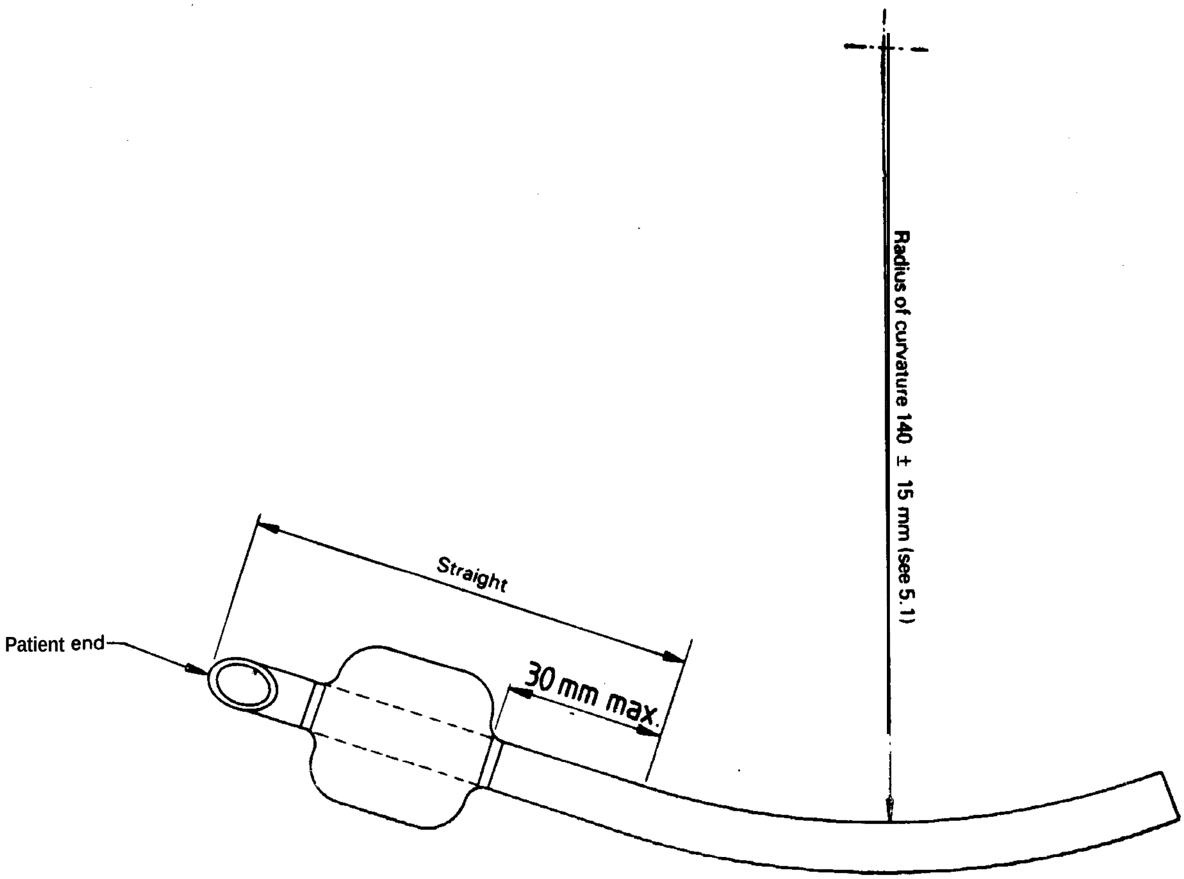

Figure 3 – Typical straight patient end (see 5.2)

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